

# SOLICITATION

## SECTION A - SOLICITATION/CONTRACT FORM

<b>1. Requisition or other Purchase Authority: P.L. 92-218 as amended</b>		
<b>2. Request for Proposal (RFP) Number:</b>  N02CM37000-11	<b>3. Issue Date:</b>  September 7, 2012	<b>4. Set Aside:</b> <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes See Part IV Section L
<b>5. Title : Development and Production of Parenteral Dosage Forms for Clinical Studies</b>		
<b>6. ISSUED BY:</b> Office of Acquisitions National Cancer Institute National Institutes of Health Riverside Five, Suite 400, Room 4025 8490 Progress Drive Frederick, MD 21701  _____ _____	<b>7. SUBMIT OFFERS TO:</b>  See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.	
<p><b>8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until <b>12:00 noon Eastern Prevailing Time on November 7, 2012.</b> Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.</b></p> <p>It is respectively requested that <b>all questions be recieved by October 24, 2012 at 2:00 P.M. Eastern Prevailing Time</b> to allow NCI adequate time to prepare and issue a response prior to the receipt of proposals. NCI will continue to accept questions up the closing date and time of the RFP, however time may not permit responses to questions recieved after October 24, 2012 to be prepared and issued prior to the receipt of proposal(s).</p>		
<p><b>9. This solicitation requires delivery of proposals as stated in ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." If proposals are required to be delivered to two different locations, the OFFICIAL POINT OF RECEIPT for determining TIMELY DELIVERY is the address provided for the OFFICE OF ACQUISITIONS.</b></p> <p><b>IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH subparagraph (c)(3) of FAR Clause 52.215-1, Instructions to Offerors--Competitive Acquisition," LOCATED IN SECTION L.1. OF THIS SOLICITATION.</b></p>		
<p><b>10. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract. <a href="http://www.ccr.gov">http://www.ccr.gov</a></b></p>		
<p><b>11. FOR INFORMATION CALL: Brenda Oberholzer, Contracting Officer</b>                  PHONE: 301-624-8750                  e-MAIL: oberholzerb@mail.nih.gov                  COLLECT CALLS WILL NOT BE ACCEPTED.</p>		
		MaryAnne Golling Contracting Officer Office of Acquisitions National Cancer Institute

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**PART I - THE SCHEDULE**

THE INFORMATION SET FORTH IN **SECTION A - SOLICITATION/CONTRACT FORM**, HEREIN CONTAINS IMPORTANT INFORMATION FOR ANY OFFEROR INTERESTED IN RESPONDING TO THIS SOLICITATION. ANY CONTRACT RESULTING FROM THIS SOLICITATION WILL INCLUDE IN ITS **SECTION A - SOLICITATION/ CONTRACT FORM**, ACCOUNTING, APPROPRIATION AND GENERAL INFORMATION APPLICABLE TO THE CONTRACT AWARD.

THE CONTRACT SCHEDULE SET FORTH IN **SECTIONS B THROUGH H**, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS NOT AN EXACT REPRESENTATION OF THE CONTRACT DOCUMENT THAT WILL BE AWARDED AS A RESULT OF THIS SOLICITATION. THE CONTRACT COST OR PRICE AND OTHER CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (i.e., those relating to the organizational structure [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the Offeror's proposal and requiring Contracting Officer Prior Approval) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

**SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS**

**ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES**

The primary objective of this project is to develop and produce pharmaceutically acceptable parenteral dosage forms of promising new agents with activity against cancer. Certain agents selected by the NCI, DCTD will be assigned for development and production as parenteral products. Batch sizes shall range from small batches (less than 100 units) to intermediate size batches to be used in Phase I and II trials; however, escalation to large batch sizes (10 - 30,000 or more units) for advanced Phase II/III trials is also possible. The capability to develop and manufacture other pharmaceutical dosage forms (i.e. large volume parenterals, sterile emulsions, liposomes and sterile micro-dispersions) is desirable.

Data obtained from resulting contracts may 1) be used to support IND applications submitted by the National Cancer Institute to the U.S. Food and Drug Administration as well as foreign agencies, 2) be provided to other NCI contractors engaged in large scale dosage form manufacture and analytical evaluation of these dosage forms and 3) be provided to physicians, pharmacists, nurses, and other medical personnel handling these products in a clinical setting.

**ARTICLE B.2. PRICES/COSTS**

- a. This is a Multiple Award Indefinite Quantity contract as contemplated by FAR 16.504. The Contractor shall be reimbursed by the Government in an amount not less than a total of \$1,000 (minimum) nor more than a total of \$6,872,139 (maximum) for successful performance of this contract.
- b. The costs set forth in this ARTICLE will cover the contract period \_\_\_\_\_ through \_\_\_\_\_.
- c. The Government will compete and award Task Orders based on the work described in SECTION C of this contract.
- d. Payments will be made from the following PRISM/NBS Line Items as follows:

PRISM/NBS Line Item No.	Line Item Description	PRISM/NBS Line Item Period of Performance	Funded Amount

- e. Ordering procedures are described in The TASK ORDER PROCEDURE Article in SECTION G of this contract.

### **ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS**

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Conferences & Meetings, 2) Food for Meals, Light Refreshments & Beverages, 3) Promotional Items, 4) Acquisition, by purchase or lease, of any interest in real property; 5) Special rearrangement or alteration of facilities; 6) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 7) Travel Costs including Foreign Travel; 8) Consultant Costs; 9) Subcontract Costs; 10) Patient Care Costs; 11) Accountable Government Property; 12) Printing costs; and 13) Research Funding.

### **ARTICLE B.4. ADVANCE UNDERSTANDINGS**

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

## SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

### ARTICLE C.1. STATEMENT OF WORK

- a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated July 10, 2012, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

### ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one hardcopy of each report shall be submitted to the Contracting Officer.

All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including specific checklists, by application, can be found at: <http://www.hhs.gov/web/508/index.html> under "Helpful Resources."

All paper/hardcopy documents/reports submitted under this contract shall be printed or copied, double-sided, on at least 30 percent post consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b).

#### a. Technical Progress Reports

1. In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award. *[Note: Beginning May 25, 2008, the Contractor shall include the applicable PubMed Central or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]*

For proposal preparation purposes only, it is estimated that in addition to the required electronic versions 1 hard copy of these reports will be required as follows:

- Monthly - Per Task Order
- Quarterly - Per Task Order
- Semi-Annually
- Annually - Per Task Order
- Annually (with a requirement for a Draft Annual Report)
- Final - Upon final completion of the contract - Upon final completion of each Task Order
- Final - Upon final completion of the contract (with a requirement for a Draft Final Report)

#### Monthly Task Order Reports

The Contractor shall provide monthly progress reports during the performance of each Task Order. These reports shall include 1) summary of progress; 2) description of activities during the period and activities planned for the ensuing reporting period; 3) summary of deliverables that have been completed, and the completion date; 4) whether activities are on schedule, whether problems were encountered, and resolutions for any problems encountered.

This report is due 15 calendar days after each reporting period. No monthly report is due when an annual report is due.

## Annual Task Order Reports

The Contractor shall provide annual progress reports during the performance of each Task Order. These reports shall include 1) summary of progress during the past 12 months; 2) description of activities during the period and activities planned for the ensuing reporting period; 3) summary of deliverables that have been completed, and the completion date; 4) whether activities are on schedule, whether problems were encountered, and resolutions for any problems encountered.

This report is due 15 calendar days after each reporting period. No monthly report is due when an annual report is due.

## Final Task Order Reports

The Contractor shall provide a Final Task Order Report upon completion of the Task Order Statement of Work. These reports shall include 1) summation of the work performed and results obtained for the entire period of performance. This report shall be in sufficient detail to comprehensively describe the results achieved.

Final reports for development Task Orders shall describe all tests performed including accelerated stability data and provide specific recommendations for production methods that could be distributed by the Government for manufacturing, and tentative specifications for vial and closure to be used.

Final reports for production Task Orders must be completed and accurate including all procedures and test performed. The report for the first batch of each new drug manufactured shall include certain parts to be used in the NCI's Investigational New Drug Application to the FDA. The project report shall include the following: manufacturer's quality control of the active drug substance, manufacturing instructions or batch record, calculations, in-process assay, manufacturing records, component certificates (e.g. for vials, stoppers, excipients), quality control of formulated product, final vial and label accounting, and description of facilities or reference to a Drug Master File.

This report is due 30 calendar days after the reporting period. No monthly or annual report is due when the final report is due.

## 2. Summary of Salient Results

The Contractor will be required to prepare and submit, with the final report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. This report will be required on or before the expiration date of the contract.

## ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Division of Extramural Inventions and Technology Resources (DEITR), OPERA, OER, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report per task order, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of each task order.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. Thereafter, reports shall be due on or before the 15th Calendar day following the reporting period. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the task order. All reports shall be sent to the following address:

Contracting Officer  
National Institutes of Health  
National Cancer Institute  
Office of Acquisition  
Riverside Five, Suite 400, Room 4025  
8490 Progress Drive

Frederick, Maryland 21701

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web ( <http://www.iedison.gov>), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

## **SECTION D - PACKAGING, MARKING AND SHIPPING**

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

The contractor is responsible for storage of the drug product batch at the labeled storage temperature until shipping instructions are provided by the Government. Once the clinical product is released per specifications for the drug product, the clinical batch must be shipped per instructions provided by the Government. In most cases, the clinical batch is packaged and shipped such that labeled temperature is maintained and monitored during shipment until delivery is made to NCI.

## **SECTION E - INSPECTION AND ACCEPTANCE**

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, the Contracting Officer's Representative is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at:  
National Institutes of Health  
National Cancer Institute  
Executive Plaza North  
6130 Executive Blvd  
Bethesda, Maryland 20892

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

- d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause **52.246-4, Inspection of Services - Fixed Price** (August 1996).

FAR Clause **52.246-5, Inspection of Services - Cost-Reimbursement** (April 1984).

**SECTION F - DELIVERIES OR PERFORMANCE****ARTICLE F.1. PERIOD OF PERFORMANCE**

The period of performance of this contract shall be from \_\_\_\_\_ through \_\_\_\_\_.

**ARTICLE F.2. DELIVERIES**

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

- a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the dates specified below and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract:

Item	Description	Quantity	Delivery Schedule
(1)	Monthly Task Order Progress Report	One (1) hard copy to the COR and one (1) electronic copy to the COR and the CO	15 calendar days following reporting period
(2)	Annual Task Order Report	One (1) hard copy to the COR and one (1) electronic copy to the COR and the CO	15 days following the reporting period
(3)	Final Task Order Report and Summary of Salient Results	One (1) hard copy to the COR and one (1) electronic copy to the COR and the CO	Must accompany each shipment of drugs to NCI
(4)	Invention Disclosure Report per Task Order	one (1) electronic copy to the the CO; one (1) hardcopy to OPERA	Required with Annual report, and the final report

- b. The above items shall be addressed and delivered to:

Addressee	Deliverable Item No	Quantity
Contracting Officer (CO) [To be named] National Cancer Institute Riverside Five, Suite 400 8490 Progress Drive Frederick, Maryland 21701	1, 2, 3, 4	One (1) electronic copy
Contracting Officer's Representative (COR) [To be named] National Cancer Institute Executive Plaza North 6130 Executive Blvd Bethesda, Maryland 20892 E-mail address to be provided	1, 2, 3	One (1) hard copy, and one (1) electronic copy
Division of Extramural Inventions and Technology Resources(DEITR) OPERA, OER, NIH 6705 Rockledge Drive, Suite 310 MSC 7980 Bethesda, Maryland 29892	4	One (1) hard copy

**ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)**

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: <http://www.acquisition.gov/comp/far/index.html>

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

**52.242-15, Stop Work Order** (August 1989) with **Alternate I** (April 1984).

**SECTION G - CONTRACT ADMINISTRATION DATA**

**ARTICLE G.1. CONTRACTING OFFICER'S REPRESENTATIVE (COR)**

The following Contracting Officer's Representative (COR) will represent the Government for the purpose of this contract:

To be specified prior to award

The COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its COR designation.

**ARTICLE G.2. KEY PERSONNEL, HHSAR 352.242-70 (January 2006)**

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

(End of Clause)

The following individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title

**ARTICLE G.3. TASK ORDER PROCEDURE**

This contract provides for the issuance of Task Orders on a negotiated basis as follows:

**a. General**

Only the Contracting Officer may issue Task Orders to the Contractor, providing specific authorization or direction to perform work within the scope of the contract and as specified in the Statement of Work. Unless specifically authorized by the Contracting Officer, the Contractor shall not commence work until a fully executed Task Order has been awarded. The Contractor may incur costs under this contract in performance of task orders and task order modifications issued in accordance with this ARTICLE.

No other costs are authorized unless otherwise specified in the contract or expressly authorized by the Contracting Officer.

**b. Requesting Task Order Proposals.**

The Contracting Officer or a designated individual may solicit responses to requirements from Contractors within a technical area covered by a task order requirement in writing. A Task Order Request for Proposals (TORFP) will be prepared and issued for each task order requirement.

Generally, the Task Order Request for Proposal (TORFP) will include but is not limited to the following:

1. Statement of Work;
2. Reporting Requirements and Deliverables;
3. Proposal Due Date and Location to Deliver Proposals;
4. Period of Performance of Task Order;
5. Anticipated type of Task Order;
6. Technical Proposal Instructions;
7. Business proposal Instructions
8. Evaluation Factors for Award

All contract clauses contained in this contract shall be incorporated in the TORFP and the resultant task order. If conflicts exist between the contract clauses and the information outlined in the task order, the contract language takes precedence over the information in the task order.

Contractors are not required to propose on all TORFPs. Those eligible Contractors that decide not to submit a proposal shall advise the Contracting Officer, in writing, of their intention not to submit a proposal on or before the closing date and time established in the TORFP. An election not to propose on a given TORFP will not negatively affect or prohibit a Contractor from competing on future TORFPs. However, it may affect the Contractor's eligibility for continuations or extensions of the resultant Task Order.

Task Orders may be awarded at any time within the contract period of performance.

Task Order proposals shall generally be limited to ten pages, excluding Curriculum Vitae/resumes.

**c. Competitive Ordering Process.**

1. All Contractors within a technical area will receive e-mail notification advising of the availability of each proposed task order requirement. All proposed task orders will incorporate all terms of this contract unless otherwise specified in the proposed task order.
2. Contractors will be provided in adequate time to prepare and submit responses based on the Contracting Officer's consideration of the estimated dollar value and complexity of proposed task order. Responses will not be considered a proposal as defined in FAR Part 15. However, the Contractor shall provide information sufficient for consideration in accordance with FAR Part 16. Each TORFP will indicate the criteria for the evaluation of proposals. The responses shall demonstrate capability for each criterion to be evaluated. Generally, the Contractor will be asked to demonstrate the following as appropriate:
  - Understanding of the requirements;
  - Experience and capability on similar tasks;
  - Technical approach, methods and procedures for satisfying the requirements with a discussion of potential problems to be encountered and proposed solutions and/or risk mitigation strategies.
  - Procedures for assuring quality of work, products, and deliverables;

- Plan for managing the task order, including meeting requirements and schedules, and performance measures (if applicable);
- Staffing plan with skill levels and level of effort for each individual proposed. Generally, resumes will be required for proposed personnel (if not previously submitted);
- References to evaluate past performance; and
- Cost/Price to perform the task order.

#### d. Evaluation and Award of Task Order Proposals

The Government will evaluate the Task Order proposals against the requirements of the TORFP. Specifically, the technical evaluation factors, cost/price, past performance and any other factor specifically identified in the TORFP will be used for evaluation of each proposal. In addition, the TORFP will identify the basis for selecting a contractor for award. Generally, technical factors will be significantly more important than cost or price. However, each TORFP will specify how the award decision will be made.

Upon completion of evaluations, the Contracting Officer will issue a task order to the Contractor whose proposal is most advantageous to the government.

The Contracting Officer will notify the Contractor(s) of the selection decision in writing.

#### e. Fair Opportunity

1. In accordance with FAR 16.505(b)(1)(i), each awardee will be given a fair opportunity to be considered for each order issued over \$3,000 unless the following exception(s) apply:
  - (i) The agency need for the supplies or services is so urgent that providing a fair opportunity would result in unacceptable delays.
  - (ii) Only one awardee is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized.
  - (iii) The order must be issued on a sole-source basis in the interest of economy and efficiency because it is a logical follow-on to an order already issued under the contract, provided that all awardees were given a fair opportunity to be considered for the original order.
  - (iv) It is necessary to place an order to satisfy a minimum guarantee.
2. All awardees will be given a fair opportunity to be considered in accordance with the FAR as follows:
  - (i) For orders exceeding \$3,000 up to the simplified acquisition threshold, in accordance with FAR 16.505(b)(1)(ii);
  - (ii) For orders exceeding the simplified acquisition threshold up to \$5 Million, in accordance with 16.505(b)(1)(iii); and,
  - (iii) For orders exceeding \$5 Million, in accordance with FAR 16.505(b)(1)(iv).

## ARTICLE G.4. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

\*For Cost- Reimbursement Task Orders Only\*

a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**

2. Payment requests shall be submitted to the offices identified below.

a. The original invoice shall be submitted to the following designated billing office

National Institutes of Health  
Office of Financial Management  
Commercial Accounts  
2115 East Jefferson Street, Room 4B-432, MSC 8500  
Bethesda, MD 20892-8500

b. One courtesy copy of the original invoice shall be submitted electronically as follows:

1. The Contractor shall scan the original payment request (invoice) in Adobe Portable Document Format (PDF) along with the necessary supporting documentation as one single attachment.
2. Save the single attachment (scanned invoice along with any supporting documentation) in the following format: YourVendorName\_Invoice number (e.g., if you are submitting Invoice 123456, save the single attachment as "ABC Company\_Invoice 123456") [Note: Please do not use special characters such as (#, \$, %, \*, &, !) when saving your attachment. Only the underscore symbol ( \_ ) is permitted.]
3. Transmit the saved single attachment via e-mail to the appropriate branch's Central Point of Distribution as identified in subparagraph 3.b. below (ncibranchinvoices@mail.nih.gov). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contract Number\_ Contract Title\_ Contractor's Name\_ unique Invoice number.

(e.g, HHSN2612XXXXC\_Clinical Genetics Support\_ABC Company\_Invoice 12345) [Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office listed in subparagraph a, above, to meet the requirements of a "proper invoice." Also, The Contractor must certify on the payment request that the electronic courtesy copy is a duplicate of the original invoice mailed to NIH's Office of Financial Management.]

3. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

- a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is **National Cancer Institute**.
- b. Central Point of Distribution. For the purpose of this contract, the **Central Point of Distribution is Branch C - ncibranchinvoices@mail.nih.gov**
- c. **Federal Taxpayer Identification Number (TIN)**. If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. [Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.] If the Contractor

has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

d. **DUNS or DUNS+4 Number.** The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. [ Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.] If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

e. Invoice Matching Option. This contract requires a **two-way match**.

f. **Unique Invoice Number.** Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

g. **Contract Title:** Beginning July 1, 2012, the contract title, located in block 15B of the first page of the contract document, shall be placed on all invoices submitted for payment.

b. E-Mail:

The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number. [Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]

c. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6088.

d. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of the above referenced contract."

## ARTICLE G.5. INVOICE SUBMISSION

\*For Fixed-Price Task Orders Only\*

a. Invoice Instructions for NIH Fixed-Price Type Contracts, NIH(RC)-2, are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**

2. Payment requests shall be submitted to the offices identified below.

a. The original invoice shall be submitted to the following designated billing office

National Institutes of Health  
Office of Financial Management  
Commercial Accounts  
2115 East Jefferson Street, Room 4B-432, MSC 8500  
Bethesda, MD 20892-8500

b. One courtesy copy of the original invoice shall be submitted electronically as follows:

1. The Contractor shall scan the original payment request (invoice) in Adobe Portable Document Format (PDF) along with the necessary supporting documentation as one single attachment.
2. Save the single attachment (scanned invoice along with any supporting documentation) in the following format: YourVendorName\_Invoice number (e.g., if you are submitting Invoice 123456, save the single attachment as "ABC Company\_Invoice 123456") [Note: Please do not use special characters such as (#, \$, %, \*, &, !) when saving your attachment. Only the underscore symbol (\_) is permitted.]
3. Transmit the saved single attachment via e-mail to the appropriate branch's Central Point of Distribution as identified in subparagraph 3.b. below (ncibranchcinvoices@mail.nih.gov). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contract Number\_ Contract Title\_ Contractor's Name\_ unique Invoice number.

(e.g, HHSN2612XXXXC\_Clinical Genetics Support\_ABC Company\_Invoice 12345) [Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office listed in subparagraph a, above, to meet the requirements of a "proper invoice." Also, The Contractor must certify on the payment request that the electronic courtesy copy is a duplicate of the original invoice mailed to NIH's Office of Financial Management.]

3. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

NOTE: A copy of the face page of the deliverable(s) shall be submitted with the invoice to designated billing office (National Institutes of Health/Office of Financial Management). Refer to Contract Section B - Prices for the payment schedule. The entire deliverable(s) shall be submitted with the invoice to the approving official (Contracting Officer).

- a. Name of the Office of Acquisitions. **The Office of Acquisitions for this contract is National Cancer Institute.**
- b. Central Point of Distribution. For the purpose of this contract, the **Central Point of Distribution is** NCI OA Branch C - ncibranchcinvoices@mail.nih.gov .
- c. **Federal Taxpayer Identification Number (TIN).** If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. [Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.] If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

- d. **DUNS or DUNS+4 Number.** The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. [ *Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.*] If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
- e. Invoice Matching Option. This contract requires a **two-way match**.
- f. **Unique Invoice Number.** Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.
- g. **Contract Title:** Beginning July 1, 2012, the contract title, located in Block 15B of the first page of the contract document, shall be placed on all invoices submitted for payment.

b. E-Mail:

The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number. [Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]

- c. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6088.
- d. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of the above referenced contract."

## ARTICLE G.6. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in PART II, SECTION I, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services  
Office of Acquisition Management and Policy  
National Institutes of Health  
6011 EXECUTIVE BLVD, ROOM 549C, MSC-7663  
BETHESDA MD 20892-7663

These rates are hereby incorporated without further action of the Contracting Officer.

## **ARTICLE G.7. GOVERNMENT PROPERTY**

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication, entitled, "HHS Contracting Guide for Contract of Government Property," which can be found at:

[http://www.hhs.gov/hhsmanuals/logisticsmanual/Appendix Q\\_HHS Contracting Guide.pdf](http://www.hhs.gov/hhsmanuals/logisticsmanual/Appendix Q_HHS Contracting Guide.pdf).

## **ARTICLE G.8. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE**

### **a. Contractor Performance Evaluations**

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluations will be prepared annually, on the anniversary of award..

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

### **b. Electronic Access to Contractor Performance Evaluations**

Contractors may access evaluations through a secure Web site for review and comment at the following address:

<http://www.cpars.gov>

## **SECTION H - SPECIAL CONTRACT REQUIREMENTS**

### **ARTICLE H.1. HUMAN SUBJECTS**

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

### **ARTICLE H.2. NEEDLE DISTRIBUTION**

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

### **ARTICLE H.3. ACKNOWLEDGEMENT OF FEDERAL FUNDING**

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

### **ARTICLE H.4. LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES**

The Contractor shall not use contract funds to support activities that promote the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established under section 202 of the Controlled Substances Act, except for normal and recognized executive-congressional communications. This limitation shall not apply when the Government determines that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

### **ARTICLE H.5. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION**

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

### **ARTICLE H.6. SUBCONTRACTING PROVISIONS**

#### **a. Small Business Subcontracting Plan**

1. The Small Business Subcontracting Plan, dated \_\_\_\_\_ is attached hereto and made a part of this contract.
2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

#### **b. Subcontracting Reports**

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at <http://www.esrs.gov>.

1. Individual Subcontract Reports (ISR)

Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:

April 30th  
October 30th  
Expiration Date of Contract

2. Summary Subcontract Report (SSR)

Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

October 30th

For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes at the following e-mail address:

To be determined prior to award  
Contracting Officer

## **ARTICLE H.7. CONFIDENTIALITY OF INFORMATION**

- a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.
- b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.
- c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.
- d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.
- e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.
- f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.
- g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

The following information is covered by this article:

Confidentiality. All data provided to the Contractor and developed by the Contractor under this contract must be treated confidentially. The data to be treated confidentially are associated not only with the certain "discreet" compounds which are not available to the public, but with all agents and processes that are under development by the National Cancer Institute (NCI). Under no circumstances are chemicals or drugs or any information associated with these chemicals or drugs, including the data generated and development processes under this contract, to be released or divulged to the public without prior written approval of the NCI Contracting Officer's Technical Representative.

The Government requires that all data accumulated under the projected contracts be immediately available for its review and that provisions be made to maintain confidentiality of all data. Authority to release data may be granted only by the Contracting Officer together with the Contracting Officer's Representative and must be in writing.

**ARTICLE H.8. PUBLICATION AND PUBLICITY**

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, under Contract No. \_\_\_\_\_"

**ARTICLE H.9. TASK ORDER/DELIVERY ORDER CONTRACT OMBUDSMAN**

In accordance with FAR 16.505(b)(5), the following individual has been designated as the NIH Ombudsman for task order and delivery order contracts.

The following individual will be included in the resultant contract as follows:

<b>For Non R&amp;D Contracts:</b>
Dr. Richard G. Wyatt
NIH Competition Advocate
1 Center Drive, Room 160, MSC 0151
Bethesda, MD 20892-0151
Phone: (301) 496-4920
FAX: (301) 402-4273
e-mail: <a href="mailto:WyattRG@mail.nih.gov">WyattRG@mail.nih.gov</a>

**ARTICLE H.10. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE**

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The e-mail address is [Htips@os.dhhs.gov](mailto:Htips@os.dhhs.gov) and the mailing address is:

Office of Inspector General  
 Department of Health and Human Services  
 TIPS HOTLINE  
 P.O. Box 23489  
 Washington, D.C. 20026

**ARTICLE H.11. YEAR 2000 COMPLIANCE**

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause(s):

- 1. **Service Involving the Use of Information Technology**  
**YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY**

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations.

(End of Clause)

## **ARTICLE H.12. CONSTITUTION DAY**

Each educational institution that receives Federal funds for a fiscal year shall hold an educational program on the United States Constitution on September 17 of such year for the students serviced by the educational institution in accordance with Public Law 108-447.

## **PART II - CONTRACT CLAUSES**

### **SECTION I - CONTRACT CLAUSES**

THE FOLLOWING ARTICLE I.1. GENERAL CLAUSE LISTING(S) WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

The complete listing of these clauses may be accessed at:

<http://oamp.od.nih.gov/DGS/generalClauses.aspx>

#### **ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS**

\*This General Clause Listing applies only to Educational Institutions\*

#### **ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT SERVICE CONTRACT**

\*This General Clause listing is applicable only to Cost-Reimbursement Task Orders\*

#### **ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE SERVICE CONTRACT**

\*This General Clause listing applies only to Fixed-Price Task Orders\*

## ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following substitution(s) will be made part of the resultant contract:

- a. FAR Clause **52.215-23, Limitations on Pass-Through Charges** (October 2009), is added.

\*This clause is only applicable to Fixed Price Task Orders\*

- b. **Alternate II** (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (January 2011) is added.

- c. FAR Clause **52.225-1, Buy American Act--Supplies** (June 2003) is deleted in its entirety and FAR Clause **52.225-3, Buy American Act--Free Trade Agreements--Israeli Trade Act** (May 2012) is substituted therefor.

Alternate I (March 2012) is not applicable to this contract.

Alternate II (March 2012) is not applicable to this contract.

Alternate III (March 2012) is applicable to this contract.

- d. **Alternate I** (April 1984), of FAR Clause **52.227-1, Authorization and Consent** (December 2007) is deleted in its entirety.

FAR Clause **52.227-11, Patent Rights--Ownership by the Contractor** (December 2007) is deleted in its entirety.

**Alternate IV** (December 2007), of FAR Clause **52.227-14, Rights In Data--General** (December 2007) is deleted in its entirety.

**Alternate II** (April 2012), of FAR Clause **52.245-1, Government Property** (April 2012) is deleted in its entirety.

\*The clauses in I.2.c. are only applicable to Educational Institutions and/or Non-Profit Organizations\*

- e. FAR Clause **52.249-4, Termination for Convenience of the Government (Services) (Short Form)** (April 1984), is deleted in its entirety and FAR Clause **52.249-2, Termination for Convenience of the Government (Fixed Price)** (April 2012) is substituted therefor.

\*This clause is only applicable to Fixed Price Task Orders\*

**ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES**

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

- 1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (April 2010).
- 2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (December 2007).

".....(3) Any required posters may be obtained as follows:

Poster(s)	Obtain From"
HHS Contractor Code of Ethics and Business Conduct Poster	<a href="http://oig.hhs.gov/fraud/report-fraud/OIG_Hotline_Poster.pdf">http://oig.hhs.gov/fraud/report-fraud/OIG_Hotline_Poster.pdf</a>

- 3. FAR Clause **52.216-18, Ordering** (October 1995).

"(a) ....Such orders may be issued from \_\_\_\_\_ [insert date] through \_\_\_\_\_ [insert date].

- 4. FAR Clause **52.216-22, Indefinite Quantity** (October 1995).

"(d) ...the Contractor shall not be required to make any deliveries under this contract after \_\_\_\_\_ [insert date]..."

- 5. FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (January 2011).

"(c) Waiver of evaluation preference.....  
 Offeror elects to waive the evaluation preference."

- 6. FAR Clause **52.219-7, Notice of Partial Small Business Set-Aside** (June 2003).

**Alternate I** (October 1995) is not applicable to this contract.

**Alternate II** (March 2004) is not applicable to this contract.

- 7. FAR Clause **52.219-14, Limitations on Subcontracting** (November 2011).

- 8. FAR Clause **52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting** (December 2010).

9. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (April 2012).
10. FAR Clause **52.223-3, Hazardous Material Identification and Material Safety Data** (January 1997), with **Alternate I** (July 1995).
11. FAR Clause **52.227-17, Rights in Data--Special Works** (December 2007).

As specified in the Deliveries Article, Final Task Order Reports must include production methods that could be distributed by the Government for manufacturing.

12. FAR Clause **52.230-2, Cost Accounting Standards** (May 2012).
13. FAR Clause **52.230-5, Cost Accounting Standards - Educational Institution** (May 2012).
14. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (June 2010).
15. FAR Clause **52.232-19, Availability of Funds for the Next Fiscal Year** (April 1984).

"Funds are not presently available for performance under this contract beyond \_\_\_\_\_."

"...No legal liability on the part of the Government for any payment may arise for performance under this contract beyond \_\_\_\_\_."

16. FAR Clause **52.237-3, Continuity of Services** (January 1991).
17. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).
18. FAR Clause **52.245-9, Use and Charges** (April 2012).
19. FAR Clause **52.251-1, Government Supply Sources** (April 2012).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

1. HHSAR Clause **352.223-70, Safety and Health** (January 2006).
2. HHSAR Clause **352.231-70, Salary Rate Limitation** (March 2012).

*Note: P.L. 112-74 sets forth the Salary Rate Limitation at the Executive Level II Rate, effective December 23, 2011.*

*See the following Web site for Executive Schedule rates of pay: <http://www.opm.gov/oca/> .*

*(For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)*

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

1. THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.

## ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

### a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

#### 1. FAR Clause **52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters** (February 2012)

(a) The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIS) on a semi-annual basis, throughout the life of the contract, by posting the required information in the Central Contractor Registration database at <https://www.acquisition.gov>.

(b) As required by section 3010 of the Supplemental Appropriations Act, 2010 (Pub. L. 111-212), all information posted in FAPIS on or after April 15, 2011, except past performance reviews, will be publicly available. FAPIS consists of two segments--

(1) The non-public segment, into which Government officials and the Contractor post information, which can only be viewed by--

- (i) Government personnel and authorized users performing business on behalf of the Government; or
- (ii) The Contractor, when viewing data on itself; and

(2) The publicly-available segment, to which all data in the non-public segment of FAPIS is automatically transferred after a waiting period of 14 calendar days, except for--

- (i) Past performance reviews required by subpart 42.15;
- (ii) Information that was entered prior to April 15, 2011; or
- (iii) Information that is withdrawn during the 14-calendar-day waiting period by the Government official who posted it in accordance with paragraph (c)(1) of this clause.

(c) The Contractor will receive notification when the Government posts new information to the Contractor's record.

(1) If the Contractor asserts in writing within 7 calendar days, to the Government official who posted the information, that some of the information posted to the non-public segment of FAPIS is covered by a disclosure exemption under the Freedom of Information Act, the Government official who posted the information must within 7 calendar days remove the posting from FAPIS and resolve the issue in accordance with agency Freedom of Information procedures, prior to reposting the releasable information. The contractor must cite 52.209-9 and request removal within 7 calendar days of the posting to FAPIS.

(2) The Contractor will also have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the associated information is retained, i.e., for a total period of 6 years. Contractor comments will remain a part of the record unless the Contractor revises them.

(3) As required by section 3010 of Pub. L. 111-212, all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available.

(d) Public requests for system information posted prior to April 15, 2011, will be handled under Freedom of Information Act procedures, including, where appropriate, procedures promulgated under E.O. 12600.

(End of clause)

2. FAR Clause **52.216-19, Order Limitations** (October 1995)

(a) **Minimum Order.** When the Government requires supplies or services covered by this contract in an amount of less than \_\_\_\_\_ [insert dollar figure or quantity], the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.

(b) **Maximum Order.** The Contractor is not obligated to honor--

(1) Any order for a single item in excess of \_\_\_\_\_ [insert dollar figure or quantity].

(2) Any order for a combination of items in excess of \_\_\_\_\_ [insert dollar figure or quantity]; or

(3) A series of orders from the same ordering office within \_\_ days that together call for quantities exceeding the limitation in subparagraph (1) or (2) above.

(c) If this is a requirements contract (i.e., includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) above.

(d) Notwithstanding paragraphs (b) and (c) above, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within 14 days after issuance, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

c. **THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.**

## PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

### SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

#### SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal (Non R & D)	<a href="#">PACKAGING.AND.DELIVERY.OF.THE.PROPOSAL.pdf</a>
Attachment 2:	Proposal Intent Response Sheet	<a href="http://rcb.cancer.gov/rcb-internet/forms/intent.jsp">http://rcb.cancer.gov/rcb-internet/forms/intent.jsp</a>
Attachment 3:	Statement of Work	<a href="#">SOW.pdf</a>
Attachment 4:	Government Furnished Property	<a href="#">GOVERNMENT.FURNISHED.PROPERTY.pdf</a>
Attachment 5:	Section K - Representations, Certifications, and Other Statements of Offerors	<a href="http://oamp.od.nih.gov/DGS/DGS_Attachments.html">http://oamp.od.nih.gov/DGS/DGS_Attachments.html</a>

#### TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 6:	Additional Technical Proposal Instructions	<a href="#">ADD.TECH.INSTRUCTIONS.pdf</a>
Attachment 7:	Sample Task Order	<a href="#">SAMPLE.TASK.ORDER.pdf</a>
Attachment 8:	Technical Proposal Cost Summary	<a href="http://oamp.od.nih.gov/DGS/FORMS/Tech-Prop-Cost-Summ.pdf">http://oamp.od.nih.gov/DGS/FORMS/Tech-Prop-Cost-Summ.pdf</a>
Attachment 9:	Summary of Related Activities	<a href="http://oamp.od.nih.gov/DGS/FORMS/summary-related-activities.pdf">http://oamp.od.nih.gov/DGS/FORMS/summary-related-activities.pdf</a>

#### BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 10:	Proposal Summary and Data Record, NIH-2043	<a href="http://oamp.od.nih.gov/DGS/FORMS/NIH2043.pdf">http://oamp.od.nih.gov/DGS/FORMS/NIH2043.pdf</a>
Attachment 11:	Small Business Subcontracting Plan	<a href="http://www.hhs.gov/about/smallbusiness/subcontractplan.html">http://www.hhs.gov/about/smallbusiness/subcontractplan.html</a>
Attachment 12:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	<a href="http://oamp.od.nih.gov/contracts/BUSCOST.HTM">http://oamp.od.nih.gov/contracts/BUSCOST.HTM</a> <a href="http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls">http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls</a>
Attachment 13:	Certificate of Current Cost or Pricing Data	<a href="http://oamp.od.nih.gov/DGS/FORMS/cert-current-cost.pdf">http://oamp.od.nih.gov/DGS/FORMS/cert-current-cost.pdf</a>
Attachment 14:	Disclosure of Lobbying Activities, OMB Form SF-LLL	<a href="http://www.gsa.gov/portal/forms/download/E0F5394ACA9DDC4085256A3E005C7420">http://www.gsa.gov/portal/forms/download/E0F5394ACA9DDC4085256A3E005C7420</a>

#### INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 15:	Invoice Instructions for NIH Fixed Price Contracts NIH(RC)-2	<a href="http://oamp.od.nih.gov/DGS/FORMS/rc2.pdf">http://oamp.od.nih.gov/DGS/FORMS/rc2.pdf</a>

<b>Attachment No.</b>	<b>Title</b>	<b>Location</b>
Attachment 16:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	<a href="http://oamp.od.nih.gov/DGS/FORMS/rc4.pdf">http://oamp.od.nih.gov/DGS/FORMS/rc4.pdf</a>
Attachment 17:	Safety and Health, HHSAR Clause 352.223-70	<a href="http://oamp.od.nih.gov/DGS/FORMS/Safety-Health-hhsar-1-06.pdf">http://oamp.od.nih.gov/DGS/FORMS/Safety-Health-hhsar-1-06.pdf</a>
Attachment 18:	Government Property Schedule	To be determined during negotiations.
Attachment 19:	Disclosure of Lobbying Activities, OMB Form SF-LLL	<a href="http://www.gsa.gov/portal/forms/download/E0F5394ACA9DDC4085256A3E005C7420">http://www.gsa.gov/portal/forms/download/E0F5394ACA9DDC4085256A3E005C7420</a>

## **PART IV - REPRESENTATIONS AND INSTRUCTIONS**

### **SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS**

#### **IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :**

1. Go to the **Online Representations and Certifications Application (ORCA)** at: <https://orca.bpn.gov/> and complete the Representations and Certifications including updates as necessary to include the NAICS Code specified in this RFP; and
2. Go to the **Central Contractor Registration (CCR)** at: <https://www.bpn.gov/ccr/default.aspx> and complete and / or update as necessary to include the NAICS Code specified in this RFP; and
3. Complete, and **INCLUDE as part of your BUSINESS PROPOSAL:**  
**SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS**  
which is included as an Attachment in Section J-LIST OF ATTACHMENTS, SOLICITATION ATTACHMENTS of this solicitation.

If you are unable to access this SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

## SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

### 1. GENERAL INFORMATION

NOTE: The offeror may submit WRITTEN questions requesting clarification of the RFP contents. Information provided with each question must include the document name, specific page, paragraph, clause or other definitive citation requiring clarification. All Questions must be submitted ELECTRONICALLY to Brenda Oberholzer at oberholzerb@mail.nih.gov. FACSIMILE, TELEPHONE OR MAILED QUESTIONS WILL NOT BE ACCEPTED.

It is respectively requested that all questions be received by October 24, 2012 at 2:00 P.M. Eastern Prevailing Time to allow NCI adequate time to prepare and issue a response prior to the receipt of proposals. NCI will continue to accept questions up the closing date and time of the RFP, however time may not permit responses to questions received after October 24, 2012 to be prepared and issued prior to the receipt of proposal(s).

All proposals submitted in response to this RFP shall have each page numbered sequentially in order to facilitate the review process. Attachments and exhibits may be excluded, provided a title appears on each submitted attachment of exhibit. It is highly desirable that each page reference the Offeror's name or other identifier in the header or footer.

**Offerors must complete and include Task Order Proposal for the attached Sample Task Order (Attachment 7) due with the Proposal submission as a separately tabbed document.**

#### a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Provision 52.215-1 (January 2006)]

(a) *Definitions.* As used in this provision--

*"Discussions"* are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

*"In writing", "writing", or "written"* means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

*"Proposal modification"* is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

*"Proposal revision"* is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

*"Time,"* if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations.* If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals.*

(1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--

(i) The solicitation number;

- (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
- (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
- (iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
- (v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

*(3) Submission, modification, revision, and withdrawal of proposals.*

(i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

- (4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.
- (5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.
- (6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.
- (7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.
- (8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date.* Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) *Restriction on disclosure and use of data.*

(1) The proposal submitted in response to this request may contain data (trade secrets; business data (e.g., commercial information, financial information, cost and pricing data); and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:

"Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services (HHS), data contained in the portions of this proposal which the offeror has specifically identified by page number, paragraph, etc. as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that HHS may not be able to withhold a record (e.g. data, document, etc.) nor deny access to a record requested pursuant to the Act and that the HHS's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if HHS has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (*insert page numbers, paragraph designations, etc. or other identification*).

(2) In addition, the offeror must mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming statement(s).

(f) *Contract award.*

- (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.
- (2) The Government may reject any or all proposals if such action is in the Government's interest.
- (3) The Government may waive informalities and minor irregularities in proposals received.
- (4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.
- (5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.
- (6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.
- (7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.
- (8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.
- (9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.
- (10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.
- (11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:
  - (i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.
  - (ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.
  - (iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
  - (iv) A summary of the rationale for award.

(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

**Alternate I** (October 1997).As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

**b. NOTICE OF PARTIAL SMALL BUSINESS SET-ASIDE**

1. General. It is the Government's intent to award one (1) of the three (3) anticipated awards resulting from this Solicitation to a small business as a set-aside. This action is based on a determination by the Contracting Officer, alone or in conjunction with a representative of the Small Business Administration, that it is in the interest of assuring that a fair proportion of Government procurement is placed with small business concerns.
2. Definitions. The term "small business concern" means a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts, and can further qualify under the size standards in this solicitation. Qualification under the size standard listed in this solicitation will be verified in the Reqs & Certs section of the System for Award Management (SAM). In addition to meeting these criteria, a small business concern submitting an offer in his own name shall furnish, in the performing the contract, only end items manufactured or produced by small business concerns in the United States or its outlying areas, provided that this additional requirement does not apply in connection with construction or service contracts.

**c. NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

1. The North American Industry Classification System (NAICS) code for this acquisition is 325412.
2. The small business size standard is Number of Employees: 750.

**d. TYPE OF CONTRACT AND NUMBER OF AWARDS**

1. It is anticipated that multiple awards will be made from this solicitation and that the awards will be made on/about February 15, 2013.

2. It is anticipated that the awards from this solicitation will be a multiple-year Indefinite Delivery Indefinite Quantity type contract with a Period of Performance of five (5) years. Task Orders under the contract could be either fixed price or cost reimbursement.
3. FAR 16.301-3 limits use of any contract type, other than firm-fixed price, to a contractor whose accounting system is adequate for determining costs applicable to the contract. To be considered for an award under this solicitation, the Offeror is required to certify, in its Business Proposal, the adequacy of its accounting system. See the paragraph entitled, Adequate Accounting System in Section L.2. Business Proposal Instructions in this solicitation for additional information about this certification.

**e. TASK ORDERS UNDER MULTIPLE AWARD INDEFINITE DELIVERY CONTRACTS**

**a. General**

The Contractor will be required provide services under the resultant contract only in performance of task orders and modifications to task orders signed by the Contracting Officer. Costs not attributed to the performance of a specific task order shall not be allowed without the prior written consent of the Contracting Officer. The Contractor will commence performance upon the receipt of a Task Order signed by the Contracting Officer. Costs for the preparation of Task Order proposals shall not be reimbursed as a direct cost under the resultant contract.

One or more task orders may be issued during the performance period of the resultant contract. If a contractor responds to a Task Order Request for Proposal (TORFP) and is the successful offeror, that Contractor will be required to accept and perform the task order issued by the Contracting Officer within the scope of the resultant contract. The government has no obligation to issue any task orders, beyond the minimum identified in SECTION B of the contract. In the event of any inconsistency between any task order and the contract, the contract shall control.

In accordance with the Federal Acquisition Streamlining Act, the Contracting Officer will provide each Contractor a "Fair Opportunity" to be considered for each Task Order awarded in excess of \$3,000, unless one of the conditions in FAR 16.505(b)(2) applies.

The competition requirements in FAR Part 6, and the policies in FAR Subpart 15.3, **DO NOT APPLY** to the task ordering process. For each requirement under the resultant contract, the government intends to provide each Contractor a fair opportunity for consideration of a task order. The Contracting Officer shall:

1. Issue a notice of intent to award a task order for services to all resultant Contractors within a technical area covered by the task order requirement. To satisfy this requirement, the Contracting Officer will provide an e-mail notifying all qualified Contractors of the requirement. The e-mail will identify how the details concerning the requirement, including a description of the work and selection criteria, will be provided, i.e. attached to the e-mail, posted on a website. Contractors will be asked to submit a response to the notice of intent, advising the government of their intent to submit a proposal or quote;
2. Afford all Contractors, within the technical area covered by the task order requirement, who are responding to the notice, a fair opportunity to submit an offer and have that offer fairly considered;
3. Consider price and cost under each order as one of the factors in the selection decision;
4. Keep submission requirements to a minimum;
5. Consider past performance on earlier task orders under this contract to the maximum extent possible. Past performance considerations shall include, but not be limited to, the Contractor's performance regarding completeness, accuracy, clarity, timeliness and cost control. If a Contractor has no past

performance on any earlier task order, past performance will be considered through other sources, such as the Contractor's original proposal.

In addition to the above, for all orders exceeding \$5 million, the Contracting Officer will consider all requirements set forth in FAR 16.505(b)(1)(iv).

**a. Exceptions to Fair Opportunity**

Contractors may not be given an opportunity to be considered for requirements in excess of \$3,000 if one of the following conditions applies:

1. The agency need for the supplies or services is so urgent that providing a fair opportunity would result in unacceptable delays.
2. Only one awardee is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized.
3. The order must be issued on a sole-source basis in the interest of economy and efficiency because it is a logical follow-on to an order already issued under the contract, provided that all awardees were given a fair opportunity to be considered for the original order.
4. It is necessary to place an order to satisfy a minimum guarantee.

**b. Requesting Task Order Proposals**

The Contracting Officer or a designated individual may solicit responses to requirements from Contractors within a technical area covered by a task order requirement in writing.

A Task Order Request for Proposals (TORFP) will be prepared and issued for each task order requirement. All contract clauses contained the resultant contract shall be incorporated in the TORFP and the resultant task order. If conflicts exist between the contract clauses and the information outlined in the task order, the resultant contract language takes precedence over the information in the task order.

**c. Competitive Ordering Process**

1. All Contractors within a technical area will receive e-mail notification advising of the availability of each proposed task order requirement. All proposed task orders will incorporate all terms of the resultant contract unless otherwise specified in the proposed task order.
2. Contractors will be provided an adequate time to prepare and submit responses based on the Contracting Officer's consideration of the estimated dollar value and complexity of proposed task order. Responses will not be considered a proposal as defined in FAR Part 15. However, the Contractor shall provide information sufficient for consideration in accordance with FAR Part 16. Each TORFP will indicate the criteria for the evaluation of proposals. The responses shall demonstrate capability for each criterion to be evaluated. Generally, the Contractor will be asked to demonstrate the following as appropriate:
  - Understanding of the requirements;
  - Experience and capability on similar tasks;
  - Technical approach, methods and procedures for satisfying the requirements with a discussion of potential problems to be encountered and proposed solutions and/or risk mitigation strategies.
  - Procedures for assuring quality of work, products, and deliverables;
  - Plan for managing the task order, including meeting requirements and schedules, and performance measures (if applicable);

- Staffing plan with skill levels and level of effort for each individual proposed. Generally, resumes will be required for proposed personnel (if not previously submitted);
- References to evaluate past performance; and
- Cost/Price to perform the task order.

**d. Evaluation and Award of Task Order Proposals**

The Government will evaluate the Task Order proposals against the requirements of the TORFP. Specifically, the technical evaluation factors, cost/price, past performance and any other factor specifically identified in the TORFP will be used for evaluation of each proposal. In addition, the TORFP will identify the basis for selecting a contractor for award. Generally, technical factors will be significantly more important than price and other factors. However, each TORFP will specify how the award decision will be made.

Upon completion of evaluations, the Contracting Officer will issue a task order to the Contractor whose proposal is most advantageous to the government.

The Contracting Officer will notify the IDIQ Contractors of the selection decision in writing.

**f. COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

**g. COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

**h. RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

**i. PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

**j. SERVICE OF PROTEST (SEPTEMBER 2006) - FAR 52.233-2**

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer  
Office of Acquisitions  
National Cancer Institute  
Riverside Five, Suite 400  
8490 Progress Drive

Frederick, Maryland 21701

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

## 2. INSTRUCTIONS TO OFFERORS

### a. GENERAL INSTRUCTIONS

#### INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

#### 1. Contract Type and General Clauses

It is contemplated that a Indefinite Delivery Indefinite Quantity type contract will be awarded. Task Orders may be either Cost-Reimbursement or Fixed Price (See General Information). Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

#### 2. Authorized Official and Submission of Proposal

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper, printed/copied double-sided, on at least 30 percent post consumer fiber paper, as required by FAR 4.302(b), and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

##### I. COVER PAGE

Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

##### II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

##### III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

#### 3. Proposal Summary and Data Record (NIH-2043)

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See SECTION J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

#### 4. Separation of Technical and Business Proposals

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See SECTION J, Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY.) However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

#### 5. Alternate Proposals

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

#### 6. Evaluation of Proposals

The Government will evaluate proposals in accordance with the factors set forth in PART IV, SECTION M of this RFP.

#### 7. Potential Award Without Discussions

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

#### 8. Use of the Metric System of Measurement

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

**Hard Metric** - - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

**Soft Metric** - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

**Dual Systems** - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

## 9. Privacy Act - Treatment of Proposal Information

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the Government Accountability Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

## 10. Selection of Offerors

- a. The acceptability of the technical portion of each contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation factors of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b. The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d. If the Government intends to conduct discussions prior to awarding a contract -
  1. Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal,

but may be considered in rating proposals for the purpose of establishing the competitive range.

2. The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NCI's policy to conduct discussions with all offerors in the competitive range, NCI reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

- e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror.
- f. The NCI reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NCI requirements. Synopses of awards exceeding \$25,000 will be published in FedBizOpps.

#### 11. ROTC Access and Federal Military Recruiting on Campus

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented ) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

#### 12. Past Performance Information

- a. Offerors shall submit the following information as part of their Business proposal.

A list of the last 3 contracts completed during the past Five years and ALL CONTRACTS currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as \$500,000 and above.

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)

3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. North American Industry Classification System (NAICS) Code

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

- b. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

### 13. **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: <http://www.acquisition.gov/far/index.html>.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a. Facilities Capital Cost of Money, FAR Clause 52.215-16, (June 2003).
- b. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
- c. Limitations on Pass-Through Charges--Identification of Subcontract Effort, FAR Provision 52.215-22, (October 2009).
- d. Single or Multiple Awards, FAR Clause 52.216-27, (October 1995).

### b. **TECHNICAL PROPOSAL INSTRUCTIONS**

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

**Note to Offerors:** Beginning May 25, 2008, the offeror shall include the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.

#### 1. **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

**a. Statement of Work**

1. Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

2. Approach

The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives. Proposals which merely restate the requirements of the Government's scope of work will not be eligible for award.

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

3. Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

4. Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments of work, as applicable, by contract year as well as for the overall contract. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

**b. Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program

**OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.**

### 1. Single Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

### 2. Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

### 3. Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

### 4. Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

## 2. Other Considerations

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

- a. Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
- b. Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
- c. Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

- d. Other factors you feel are important and support your proposed research.
- e. Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

### 3. Technical Evaluation

Proposals will be technically evaluated in accordance with SECTION M - Evaluation Factors for Award of this solicitation.

## c. BUSINESS PROPOSAL INSTRUCTIONS

### 1. Basic Cost/Price Information

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

### 2. Salary Rate Limitation in Fiscal Year 2012

Offerors are advised that pursuant to P.L. 112-74, no NIH Fiscal Year 2012 (October 1, 2011 - September 30, 2012) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level II\* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level II\*. The salary rate limitation set by P.L 112-74 applies only to Fiscal Year 2012 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level II\* annual salary rate limitation also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L.112-74 states:

"None of the funds appropriated in this title shall be used to pay the salary of an individual through a grant or other extramural mechanism, at a rate in excess of Executive Level II."

**LINK TO EXECUTIVE SCHEDULE RATES OF PAY:** <http://www.opm.gov/oca/>

*(For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)*

**\*Note to Offerors:** The current Fiscal Year Executive Level II Salary Rate shall be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year Executive Level II Salary rates.

### 3. Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of \$650,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, See SECTION J - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

- a. THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
- b. The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.
- c. The offeror understands that:
  1. No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
  2. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.
  3. If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.
  4. Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.
  5. It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.
  6. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.
- d. Each plan must contain the following:
  1. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
  2. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small,

Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

3. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.
4. A description of the method used to develop the subcontracting goals.
5. A description of the method used to identify potential sources for solicitation purposes.
6. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
7. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
8. A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
9. Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of \$650,000 adopt a plan similar to the plan agreed upon by the offeror.
10. Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (Individual Subcontract Reports (ISRs) and Summary Subcontract Reports (SSRs) to the Government.
11. List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained in the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

28% for Small Business; 5% for Small Disadvantaged Business; 5% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

#### **4. Mentor-Protégé Program, HHSAR 352.219-70 (January 2010)**

- a. Large business prime contractors serving as mentors in the HHS Mentor-Protégé program are eligible for HHS subcontracting plan credit, and shall submit a copy of their HHS Office of Small and Disadvantaged Business Utilization (OSDBU)-approved mentor protégé agreements as part of their offers. The amount of credit provided by the Contracting Officer to a mentor firm for protégé firm developmental assistance costs shall be calculated on a dollar for dollar basis and reported by the mentor firm in the Summary Subcontract Report via the Electronic Subcontracting Reporting System (eSRS) at <http://www.esrs.gov>. The mentor firm and protégé

firm shall submit to the Contracting Officer a signed joint statement agreeing on the dollar value of the developmental assistance the mentor firm provided. (For example, a mentor firm would report a \$10,000 subcontract awarded to a protégé firm and provision of \$5,000 of developmental assistance as \$15,000 of developmental assistance.) The mentor firm may use this additional credit towards attaining its subcontracting plan participation goal under this contract.

b. The program consists of--

- i. Mentor firms--large businesses that: (i) demonstrate the interest, commitment, and capability to provide developmental assistance to small business protégé firms; and (ii) have a Mentor-Protégé agreement approved by HHS' OSDBU;
- ii. Protégé firms--firms that: (i) seek developmental assistance; (ii) qualify as small businesses, veteran-owned small businesses, service-disabled veteran-owned small businesses, HUBZone small businesses, small disadvantaged businesses, or woman-owned businesses; and (iii) have a Mentor-Protégé agreement approved by HHS' OSDBU; and
- iii. Mentor-Protégé agreements--joint agreements, approved by HHS' OSDBU, which detail the specific terms, conditions, and responsibilities of the mentor-protégé relationship.

(End of provision)

## 5. HUBZone Small Business Concerns

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at <http://www.sba.gov/hubzone>.

## 6. Extent of Small Disadvantaged Business Participation

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed \$650,000 (\$1.5 million for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b)). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth in Section M - Evaluation Factors for Award shall be used for evaluation purposes.

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: <http://www.sba.gov/size>

The Department of Commerce website for the annual determination for NAICS codes\* is: <http://www.acquisition.gov/References/sdbadjustments.htm>.

*\* Note: Public Law 103-355 which authorized the SDB Price Evaluation Adjustment (PEA) and associated percentages/factors expired on December 9, 2004, therefore, the percentages shown at this website are no longer applicable.*

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the Prime Contractor, that includes any joint ventures and

team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

#### EXAMPLE

##### Targets for SDB Participation - NAICS Industry Subsector 223

	<b>SDB Percentage of Total Contract Value</b>	<b>SDB Dollars</b>
Total Contract Value- \$1,000,000	25%	\$250,000
SDB Participation by Prime	10%	\$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	\$150,000

\*Note: FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential Prime Contractor, or a potential Prime Contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

## 7. Total Compensation Plan

### a. Instructions

1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors as a part of their Business Proposal will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

2. The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

**b. Evaluation**

**1. Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

**2. Cost (Professional Compensation)**

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

**3. Other (Labor Relations)**

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

**4. Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees.

**8. Other Administrative Data**

**a. Property**

1. It is HHS policy that Contractors will provide all property necessary for contract performance. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by the Contracting Officer. If the offeror requests that Government property be provided, other than that specified under "Government Furnished Property,"

below , the proposal must include a comprehensive justification addressing the following items:

- a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.
- b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

## 2. Government Property

The offeror shall identify Government property in its possession which it proposes to use in the performance of the prospective contract as follows:

- a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);
- b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;
- c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and
- d. A description of the offeror's property management system, plan, and any customary commercial practices, voluntary consensus standards, or industry-leading practices and standards to be used in the offeror in managing Government property.

**NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from an offeror or contractor possessing Government property. This will be done by adjusting the offers by applying, for evaluation purposes only, a rental equivalent evaluation factor, as specified in FAR 52.245-9.**

## 3. Government-Furnished Property

A Listing of Government Furnished Property is provided in Section J - Solicitation Attachments of this solicitation

4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, "HHS Contracting Guide for Contract of Government Property," which can be found at: [http://www.hhs.gov/hhsmanuals/logisticsmanual/Appendix Q\\_HHS Contracting Guide.pdf](http://www.hhs.gov/hhsmanuals/logisticsmanual/Appendix Q_HHS Contracting Guide.pdf)

- b. **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (MAY 1999)**

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232 34, Payment by Electronic Funds Transfer Other than Central Contractor Registration.

- (1) The solicitation number (or other procurement identification number).
- (2) The offeror's name and remittance address, as stated in the offer.
- (3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
- (4) The name, address, and 9 digit Routing Transit Number of the offeror's financial agent.
- (5) The offeror's account number and the type of account (checking, savings, or lockbox).
- (6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
- (7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9 digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

(End of Provision)

#### c. **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

#### d. **Adequate Accounting System**

FAR Part 16 sets forth the requirements and limitations for consideration of contract type. As stated in Section L.1., General Instructions of this solicitation, the resultant contract will not be Firm-Fixed Price. Therefore, the offeror's/contractor's accounting system and practices must be adequate and suitable for accumulating costs under government contracts.

To be considered for an award under this solicitation, the offeror shall include, in the Business Proposal, the following Certification:

"By submission of its signed offer, the Offeror certifies that its accounting system:

- Complies with generally accepted accounting principles (GAAP).
- Provides for:
  - Proper segregation of direct costs from indirect costs.
  - Identification and accumulation of direct costs by contract.
  - A logical and consistent method for the allocation of indirect costs to intermediate and final cost objectives.
  - Accumulation of costs under general ledger control.
  - A timekeeping system that identifies employees' labor by intermediate or final cost objectives.

- A labor distribution system that charges direct and indirect labor to the appropriate cost objectives.
- Interim (at least monthly) determination of costs charged to a contract through routine posting of books of account.
- Exclusion from costs charged to government contracts of amounts that are not allowable in terms of FAR 31, "Contract Cost Principles and Procedures," or other contract provisions.
- Identification of costs by contract line item and by units (as if each unit or line item were a separate contract) if required by the proposed contract.
- Segregation of preproduction costs from production costs (applies primarily to manufacturing contracts).
- Provides financial information required by contract clauses concerning limitation of cost (FAR 52.232-20 and 21) or limitation on payments (FAR 52.216-16).
- Provides financial information required to support requests for progress payments.
- Ability to develop adequate reliable data for use in pricing follow-on acquisitions.
- Accounting system is in full operation."

e. **Facilities Capital Cost of Money**, FAR 52.215-16, (June 2003)

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

**Fac Cap Cost of Money (Has)** The prospective Contractor **has** specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

**Fac Cap Cost of Money (Has Not)** **has not** specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

9. **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a. **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

**b. Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

**c. Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

**d. Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

**e. Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

**10. Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

- a. Willingness to perform as a subcontractor for specific duties (list duties).
- b. What priority the work will be given and how it will relate to other work.
- c. The amount of time and facilities available to this project.
- d. Information on their cognizant field audit offices.
- e. How rights to publications and patents are to be handled.
- f. A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

<http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm>

**11. Proposer's Annual Financial Report**

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

**12. Travel Costs/Travel Policy**

**a. Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

**b. Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

## SECTION M - EVALUATION FACTORS FOR AWARD

1. **PLEASE NOTE:** The Offeror shall submit a separate and unique technical and business proposal for the IDIQ contract, and for the Sample Task Order. The IDIQ contract, and Sample Task Order will be evaluated together based on the evaluation factors provided below and selected Offerors will receive an award for the IDIQ contract.

### 2. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost. The Government intends to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed factors listed below.

### 3. COST/PRICE EVALUATION

Offeror(s) cost/price proposal will be evaluated for reasonableness. For a price to be reasonable, it must represent a price to the government that a prudent person would pay when consideration is given to prices in the market. Normally, price reasonableness is established through adequate price competition, but may also be determined through cost and price analysis techniques as described in FAR 15.404.

Cost Realism: The specific elements of each offeror(s) proposed costs are realistic when the proposed cost elements are evaluated and found to: 1) be realistic for the work to be performed; 2) reflect a clear understanding of the requirements; and 3) be consistent with the unique methods of performance and materials described in the offeror(s) technical proposal.

Cost Realism will be evaluated only on the offeror(s) inputs which the Government will use to determine the most probable cost to perform the contract in a manner consistent with the offeror's proposal. Cost realism analysis will be conducted in accordance with FAR 15.404-1(d). The result of the cost realism analysis will be considered in the making the best value tradeoff decision.

### 4. MANDATORY QUALIFICATION CRITERIA

Listed below are mandatory qualification criteria. THE OFFEROR SHALL INCLUDE ALL INFORMATION WHICH DOCUMENTS AND/OR SUPPORTS THE QUALIFICATION CRITERIA IN ONE CLEARLY MARKED SECTION OF ITS TECHNICAL PROPOSAL.

The qualification criteria establishes conditions that must be met at the time of receipt of Final Proposal Revisions (FPRs) by the Contracting Officer in order for your proposal to be considered any further for award.

The Offeror must be registered with the FDA as a pharmaceutical manufacturing facility for sterile products. The Offeror must show proof (FDA form 483) of the most recent routine FDA inspection(s). The Offeror must be in compliance with FDA requirements during the course of contract performance, and will be required to notify the COR and CO/CS of any outstanding FDA

form FD 483's resulting from routine inspection and proposed timetable for corrective action during the course of contract performance.

## 5. TECHNICAL EVALUATION FACTORS

The evaluation factors are used by the technical evaluation committee when reviewing the technical proposals. The factors below are listed in the order of relative importance with weights assigned for evaluation purposes. Subfactors are listed in order of relative importance.

### a. Technical Approach

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A detailed Technical Approach that demonstrates a clear understanding of the draft SOW with discussions of a) formulation development; b) production of parenteral dosage forms; c) quality assurance and evaluation and d) packaging and labeling of finished products. Standard Operating Procedures used in the preparation and manufacture of dosage forms should be described as well as Standard Operation Procedures for protecting personnel from cytotoxic agents being formulated and quality control tested.

### b. Personnel

35

Personnel described must have experience with parenteral product development, especially freeze-drying, as well as expertise in the areas of sterile emulsions, liposomes and microdispersions. In addition, staff should possess experience with a variety of analytical instrumentation and the development of stability indicating assays.

### c. Facilities and Equipment

15

Demonstrate the availability of resources, equipment, and facilities as required for the performance of the tasks stated in the SOW. Specifically, addressing the following three areas:

(1) Suitability and availability of appropriate facilities including laboratory space and equipment.

(2) Availability of essential modern equipment such as:

Vial washing facilities; autoclave (state capacity) and approved water for injection holding and distribution system; Hot air stabilizer (state capacity); Automated filling equipment; Production freeze drier(s) (state capacity); Sterilizing filtration equipment (state size and capacity); compounding tanks (state capacity); Sterile preparation area; labeling and packaging equipment; inspection station; emergency support system for freeze drier(s); molecular filtration apparatus for removal of pyrogens and/or particulates; High performance liquid chromatograph (HPLC with variable wavelength detector and/or diode array detector, evaporative light scattering detector); Recording ultraviolet visible spectrophotometer; pH meter; Karl Fischer water analyzer; water bath for solubility/stability studies; infrared spectrophotometer; Pilot freeze drier (1 sq. ft. minimum shelf capacity); Melting point apparatus; and analytical balance.

### d. Organizational Experience and Capability

15

Demonstrate the organizational experience and capability as required for the performance of the tasks stated in the SOW. Specifically, addressing the following three areas:

(1) Demonstrate pertinent background experience and qualifications of the organization particularly with projects involving development and production of specialty parenteral formulations.. (i.e. How long company has been in business, what experience the company has with chemical syntheses, etc...)

(2) A special notation should be made of similar or related programs performed for the Government including documentation with reference to applicable contract numbers and supervising agencies.

(3) Evidence of organizational support.

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**Total 100**

## 6. PAST PERFORMANCE FACTOR

Offerors' past performance information will be evaluated prior to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

## 7. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

**SDB participation will not be scored**, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

- a. Extent to which SDB concerns are specifically identified
- b. Extent of commitment to use SDB concerns
- c. Complexity and variety of the work SDB concerns are to perform
- d. Realism of the proposal
- e. Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
- f. Extent of participation of SDB concerns in terms of the value of the total acquisition.

## 8. SUSTAINABILITY PLAN

The Offeror's proposal must demonstrate compliance with FAR 23.1, "Sustainable Acquisition Policy" and the interim rule entitled "Sustainable Acquisition" at <http://www.gpo.gov/fdsys/pkg/FR-2011-05-31/pdf/2011-12851.pdf> (FAR case 2010-001, FAC 2005-52). If the proposal does not include a Sustainable Acquisition Plan that addresses the environment products and services to be utilized under the resulting contract, or if the Plan is considered to be "poor" and the Government includes your proposal in the competitive range, the Offeror will be afforded the opportunity to further discuss, clarify, or modify the Plan during discussions and in their Final Proposal Revision (FPR). The Government is seeking to determine whether the Offeror has demonstrated a commitment to advance sustainable products and services.

The following evaluation criterion will be used in review of the Sustainable Acquisition Plan:

Descriptor	Proposal qualities
Excellent	Documents compliance with relevant environmental laws and regulations to acquire supplies and services that promote energy and water efficiency, advance the use of renewable energy products, and help foster markets for emerging technologies. Implements cost- effective contracting preference programs promoting energy- efficiency, water conservation and the acquisition of environmentally preferable products and services (e.g., computer monitor, desktop computer, notebook computer and personal computer products). Minimizes the procurement of materials and substances that contribute to the depletion of stratospheric ozone. Gives preference to the procurement of alternative chemical, product, and manufacturing processes that reduce overall risks to human health and the environment by lessening the depletion of ozone in the upper atmosphere. Reduces paper use and acquires paper containing at least 30% postconsumer fiber.
Good	Documents compliance with relevant environmental laws and regulations and commits the organization to more aggressive actions such as: Develops and implements innovative policies and practices to reduce scope 3 GHG emissions in HHS operations. Manages existing buildings to reduce energy, water, and materials consumption. Implements and achieves objectives in EPA's Storm water Management Guidance. Reduces paper use and acquires paper containing at least 30% postconsumer fiber. Minimizes the acquisition, use, and disposal of toxic and hazardous materials. Employs environmentally sound practices for the disposition of all agency excess or surplus electronic products. Procures Energy Star and FEMP-designated electronic equipment. Continues implementation of existing Environmental Management System (EMS) programs.
Fair	Documents existing programs that meet relevant environmental laws and regulations and proposes modest further steps.
Poor	Merely states that the offeror will comply with relevant environmental laws and regulations, or describes programs that merely comply with relevant laws.